

### AMENDMENTS TO THE DRAWINGS

The attached one sheet of drawings includes changes to Fig. 1. This sheet, which includes only one Figure, replaces the original sheet including only Fig. 1. In Fig. 1, the rectangular boxes for the stimulation unit and the control unit have been labelled with descriptive text and the corresponding numerical reference numerals 30 and 32, which are used in the specification, have been provided. Also, an error in the labelling of one of the rectangular boxes has been corrected by changing the label from  $A_{RP}$  to  $A_{LS}$ . The corrected label,  $A_{LS}$ , corresponds to a left atrial sensing unit. Similarly, the label  $A_{RS}$  corresponds to a right atrial sensing unit, and the label  $V_S$  corresponds to a ventricular sensing unit. No new matter has been added.

Attachment:           One Replacement Sheet  
                          One Annotated Sheet Showing Changes

## **REMARKS**

### **Claim status**

Claims 1-16 were pending in the case at the time of the current Office Action. Claim 1 is currently amended herein to clarify the language. Claims 1-16 are currently pending in the application.

### **Specification rejections**

In the current Office action, the Examiner is requiring a new title stating that the current title is not descriptive.

Applicants have amended the TITLE herein to comply with the Examiner's requirement.

Applicants have amended paragraph [0001] herein simply to indicate that examples of the "at least one sensing unit" are illustrated in Fig. 1 as the sensing units  $A_{LS}$ ,  $V_S$ , and  $A_{RS}$ .

Applicants respectfully request that the specification amendments be entered and that the objections be withdrawn.

### **Section 112 rejections**

In the current Office action, claims 3 and 7 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The Examiner is of the opinion that the "further sensing unit" limitation does not have support in the specification.

Applicants respectfully traverse the foregoing rejections in view of the above pending claims and for reasons set forth hereafter.

Paragraph [0001] of the specification states, "The invention concerns a biatrial triple-chamber cardiac pacemaker comprising at least one sensing unit (e.g.,  $A_{LS}$ ,  $V_S$ , and  $A_{RS}$  of Fig. 1) for detecting signals related to a natural contraction of an atrium and a ventricle of a heart and

at least one stimulation unit which is adapted to produce stimulation pulses for the stimulation of a second atrium and the ventricle of the heart. The cardiac pacemaker further includes a control which is connected to the sensing unit and the stimulation unit and which is adapted to evaluate at least the atrial sense events associated with the first atrium and the ventricular sense events associated with the ventricle, for actuation of the stimulation unit. Actuation is effected having regard to a ventricular escape interval and possibly a postatrial ventricular blanking time in such a way that a right-atrial sense event triggers the ventricular escape interval, at the end of which a ventricular stimulation pulse is triggered if same is not inhibited by a ventricular sense event within the ventricular escape interval and possibly outside the postatrial ventricular blanking time. Actuation is further effected having regard to an interatrial conduction time in such a way that a right-atrial sense event triggers the interatrial conduction time, at the end of which a left-atrial stimulation pulse is triggered which is possibly inhibited by a left-atrial sense event within the atrial conduction time.”

From paragraph [0001] and Fig. 1 it is clear that there can be more than one sensing unit (i.e., “at least one sensing unit”) and that three such sensing units ( $A_{LS}$ ,  $V_S$ , and  $A_{RS}$ ) are shown in Fig. 1, where  $A_{LS}$  is the sensing unit corresponding to the left atrium (e.g., a first sensing unit) and  $A_{RS}$  is a sensing unit for the right atrium (e.g., a second or further sensing unit).

Therefore, in view of at least the foregoing, it is respectfully submitted that there is support in the specification for “further sensing unit”.

Applicants respectfully request that the rejection of claims 3 and 7 under 35 U.S.C. 112, first paragraph, be removed.

In the current Office action, claim 1 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The Examiner takes the position that the phrase “at the same time a time interval from the last occurrence of the ventricular event ascertained outside a crosstalk window, to the next possible ventricular stimulation event,” is not clear.

Applicants respectfully traverse the foregoing rejections in view of the above pending claims and for reasons set forth hereafter.

Claim 1 has been amended herein to clarify the language in question. It should now be clear from the language of claim 1 that there are two conditions that are to be fulfilled simultaneously in order to inhibit a second atrium stimulation pulse:

- a) a ventricular sense event has occurred in the crosstalk window, and
- b) the time interval between the last ventricular event sensed outside the crosstalk window and the next possible (i.e., scheduled) ventricular stimulation event is greater than a predetermined maximum value.

Therefore, in view of at least the foregoing, it is respectfully submitted that the language of claim 1 is now clear.

Applicants respectfully request that the rejection of claim 1 under 35 U.S.C. 112, second paragraph, be removed.

### **Section 103 rejections**

In the current Office action, claims 1-16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Limousin (U.S. Patent No. 5,514,161).

Applicants respectfully traverse the foregoing rejections in view of the above pending claims and for reasons set forth hereafter.

Independent claim 1 recites a biatrial triple-chamber pacemaker for use with a heart having a first and a second atrium and a first and a second ventricle, said pacemaker comprising:  
at least one sensing unit for sense events of the first atrium and the first ventricle;  
at least one stimulation unit which is adapted to produce stimulation pulses to the second atrium and the first ventricle; and

a control unit which is connected to the sensing unit and the stimulation unit and which is adapted to evaluate, for actuating the stimulation unit, at least the atrial sense events (A<sub>R</sub>-Sense) associated with the first atrium and the ventricular sense events (V-Sense) associated with the first ventricle;

wherein the stimulation unit is actuated with regard to a ventricular escape interval and a postatrial ventricular blanking time such that an occurrence of the atrial sense event ( $A_R$ -Sense) triggers the ventricular escape interval, at the end of which a ventricular stimulation pulse is triggered if same is not inhibited by an occurrence of the ventricular sense event within the ventricular escape interval and outside the postatrial ventricular blanking time,

wherein the stimulation unit is actuated with regard to an interatrial conduction time such that an occurrence of the atrial sense event ( $A_R$ -Sense) triggers the interatrial conduction time, at the end of which a stimulation pulse to the second atrium is triggered if the stimulation pulse to the second atrium is not inhibited, and

wherein the stimulation unit is actuated such that the delivery of a stimulation pulse to the second atrium is suppressed when previously an occurrence of the ventricular sense event occurs in a crosstalk window which adjoins a postatrial ventricular blanking time and at the same time a time interval, between a last ventricular sensed event occurring outside the crosstalk window and a next possible (scheduled) ventricular stimulation event, is greater than a predetermined maximum value.

Independent claim 2 recites a biatrial triple-chamber cardiac pacemaker for use with a heart having a first and a second atrium and a first and a second ventricle, said pacemaker comprising:

at least one sensing unit for sense events of the first atrium and the first ventricle;

at least one stimulation unit which is adapted to produce stimulation pulses to the second atrium and the first ventricle; and

a control unit which is connected to the sensing unit and the stimulation unit and which is adapted to evaluate, for actuating the stimulation unit, at least the atrial sense events ( $A_R$ -Sense) associated with the first atrium and the ventricular sense events (V-Sense) associated with the first ventricle;

wherein the stimulation unit is actuated with regard to a ventricular escape interval and a postatrial ventricular blanking time such that an occurrence of the atrial sense event ( $A_R$ -Sense) triggers the ventricular escape interval, at the end of which a ventricular stimulation pulse is

triggered if same is not inhibited by an occurrence of the a ventricular sense event within the ventricular escape interval and outside the postatrial ventricular blanking time;

wherein the stimulation unit is actuated with regard to an interatrial conduction time such that an occurrence of the atrial sense event ( $A_R$ -Sense) triggers the interatrial conduction time, at the end of which a stimulation pulse to the second atrium is triggered if the stimulation pulse to the second atrium is not inhibited; and

wherein the stimulation unit is actuated such that the delivery of a stimulation pulse to the second atrium is suppressed when a ventricular sense event occurs during an upper tracking interval operating mode in which the cardiac pacemaker works at a predetermined maximum stimulation rate.

It is respectfully submitted that Limousin (U.S. Patent No. 5,514,161), hereinafter Limousin, does not teach or suggest the claimed invention of independent claim 1 or independent claim 2. According to Limousin, both atria of the heart are always paced simultaneously, since both atrial leads (6 and 7) are connected by Y-connector (5). There is only one single atrial circuit (24). Please see Fig. 1, the abstract, and column 3 line 63 to column 4 line 3. Therefore, there cannot be anything like an interatrial interval between activation of the right atrium and the left atrium.

However, providing an interatrial conduction time is an essential feature of the claimed biatrial triple chamber pacemaker of claim 1 and claim 2. According to the claimed inventions of claim 1 and claim 2, a right atrial event ( $A_R$ -Sense) triggers the interatrial conduction time at the end of which a left (i.e., second) atrial stimulus is triggered unless it is inhibited. No such teaching or suggestion is apparent from Limousin since a provision of an interatrial conduction time is not possible with the arrangement of Limousin, as described previously herein.

Furthermore, the crosstalk window of claim 1 is neither identical nor equivalent to the listening window of Limousin, as suggested by the Examiner, since the crosstalk window immediately adjoins a postatrial ventricular blanking time that is triggered by a ventricular event. In contrast, the listening window of Limousin adjoins an interval that is started with an atrial interval of a preceding heart cycle and ends with an atrial event in the next heart cycle (see column 5, lines 39 to 65 of Limousin).

The subject matter of the claimed invention of claim 1 requires that two conditions are fulfilled simultaneously in order to inhibit a left atrial stimulation pulse:

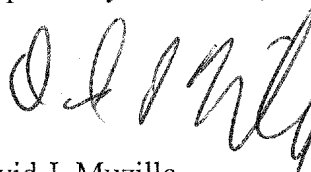
- a) a ventricular sense event has occurred in the crosstalk window, and
- b) the time interval between the last ventricular event sensed outside the crosstalk window and the next possible (scheduled) ventricular stimulation event is greater than a predetermined maximum value.

No such conditions are taught or suggested in Limousin.

Therefore, in view of at least the foregoing, it is respectfully submitted that independent claim 1 and independent claim 2 are not unpatentable over Limousin, and it is respectfully submitted that independent claim 1 and independent claim 2 each define allowable subject matter. Also, since claims 2-16 depend either directly or indirectly from claim 1 or claim 2, it is respectfully submitted that claims 2-16 define allowable subject matter as well. Applicants respectfully request that the rejection of claims 1-16 under 35 U.S.C. 103(a) be removed.

Accordingly, the applicant respectfully requests reconsideration of the rejections and objections based on at least the foregoing. After such reconsideration, it is urged that allowance of claims 1-16 will be in order.

Respectfully submitted,



David J. Muzilla  
Registration No. 50,914

Hahn Loeser & Parks LLP  
One GOJO Plaza  
Suite 300  
Akron, OH 44311-1076  
(330) 864-5550  
Fax 330-864-7986  
djmuzilla@hahnlaw.com

**CUSTOMER No. 021324**